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RHEUMATOLOGY

Guidelines

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**BSR and BHPR rheumatoid arthritis guidelines on eligibility criteria for the first biological therapy**

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**Key words:** Rheumatoid arthritis, Drug therapy, Biologics, Guidelines, Eligibility criteria, Health economics.

**Introduction and objectives**

Why do we need RA Guidelines for eligibility for the first biological therapy?

Biological therapies represent a huge advance in the management of RA. They are monoclonal antibodies or soluble receptors that specifically block mediators of inflammation or autoimmunity (cytokines, receptors and cells). Biological therapies have the following major advantages over conventional DMARDs:

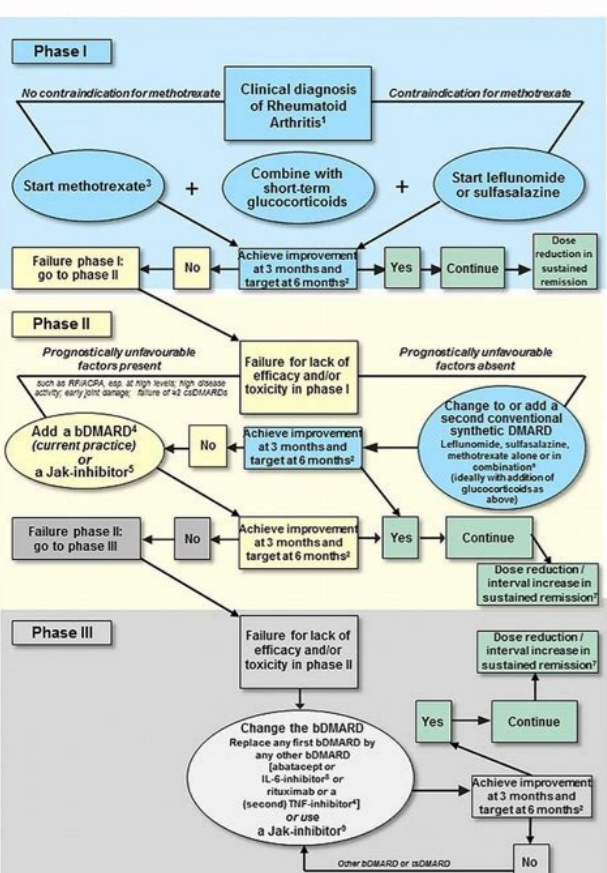
(i) their development followed an increased understanding of pathogenesis of inflammatory arthritis;

- (ii) their target is highly specific, with the mode of action easier to elucidate than with traditional DMARDs;
- (iii) their use in clinical practice has added to the confidence of health-care professionals and patients to be able to satisfactorily control disease resistant to conventional therapies, and remission of disease is an increasingly realistic aim; and
- (iv) for anti-TNF drugs, and some of the newer biological drugs, their action is usually rapid, with good symptom control, and significantly greater slowing of radiological progression than conventional DMARDs [1].

Consequently, it is important that these drugs are available to patients with inflammatory arthropathies, who fail to respond to conventional DMARD therapy, and that the best use is made of them. A drawback of biological therapies is that they are expensive compared with conventional DMARDs, and thus their unrestricted use would be unaffordable. Deciding what constitutes a cost-effective use of biological therapies has been a source of considerable debate. In the UK, the National Institute of Health and Clinical Excellence (NICE), professional and patient representative bodies and the pharmaceutical industry have interpreted the available evidence very differently. All parties agree that there is a need to make these drugs available to those patients most likely to

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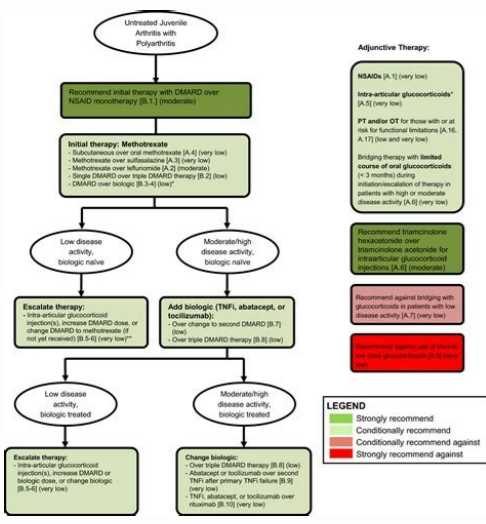


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Intervention Category (Number of Trials)	Examples of Interventions	Individual Trial Quality Analysis Risk of Bias*			Between Trials Analysis <i>Levels of Evidence</i> **; Trial Outcome Measures (Primary constructs only)
		Low	High	Un- known	
Disease Education (3)	<ul style="list-style-type: none"> <li>Drug information leaflet</li> <li>Weekly educational program</li> </ul>			3	<ul style="list-style-type: none"> <li>Level 3: Quality of life</li> <li>Level 4: Disease specific knowledge</li> </ul>
Pain Management (1)	<ul style="list-style-type: none"> <li>Pain Coping Skills Training</li> </ul>	1			<ul style="list-style-type: none"> <li>Level 3: Joint pain; Problem-focused coping; Emotion-focused coping; Coping efficacy</li> <li>Level 4: Pain days; Mood</li> </ul>
Psychosocial Intervention (4)	<ul style="list-style-type: none"> <li>Autogenic training</li> <li>Written disclosure</li> <li>Spoken disclosure</li> </ul>	2	2		<ul style="list-style-type: none"> <li>Level 1: Pain rating; Disease activity</li> <li>Level 3: Mood; Anger; Tension</li> <li>Level 4: Quality of life</li> </ul>
Joint Protection & Energy Conservation (3)	<ul style="list-style-type: none"> <li>Individual joint protection sessions w/theoretical base</li> </ul>	1	2		<ul style="list-style-type: none"> <li>Level 2: Joint protection behaviors</li> <li>Level 3: Pain rating; Patient health status; Physical function; Self-reported symptoms; Social interaction</li> <li>Level 4: Disease activity; psychological functioning; Work</li> </ul>
Combination (10)	<ul style="list-style-type: none"> <li>Cognitive behavioral therapy</li> <li>Multidisciplinary education</li> <li>Therapeutic education &amp; functional readaptation</li> </ul>	8	1	1	<ul style="list-style-type: none"> <li>Level 1: Disease knowledge; Disease activity</li> <li>Level 3: Physical functioning; Psychological functioning; Social functioning; Fatigue impact</li> <li>Level 4: Pain rating; Patient health status; Functional status; Overall symptoms</li> </ul>

\*Risk of bias criteria obtained from Cochrane's quality checklist for randomized studies: Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from [www.cochrane-handbook.org](http://www.cochrane-handbook.org).

\*\* Criteria for levels of best evidence obtained from previous exemplar study: van Tulder, M. W., Cherkun, D. C., Berman, B., Lao, L., & Koes, B. W. (1999). The effectiveness of acupuncture in the management of acute and chronic low back pain: a systematic review within the framework of the Cochrane Collaboration Back Review Group. *Spine*, 24(11), 1113-1123.



Joint protection techniques for rheumatoid arthritis occupational therapy. Rheumatoid arthritis occupational therapy exercises. Impact of rheumatoid arthritis on occupational performance. How does occupational therapy help rheumatoid arthritis.

Occupational Therapists (OTs) work either in hospitals or in the community. They help people overcome problems in everyday tasks caused by their rheumatoid arthritis and offer advice on how to protect joints from further damage, aids, equipment and adaptations. Most people we interviewed had seen an OT either soon after diagnosis, or for specific problems or after surgery. The advice offered by OTs was described as 'brilliant' (see Interview 16 below), 'really good' and 'quite helpful' by most people although two people felt that the OT had been less knowledgeable than they would have liked, particularly about aids for work, and had not fulfilled promises of providing equipment and further information. One woman felt exasperated that she had to explain her ongoing problems to a different OT each time she was referred at the same hospital and that there was little continuity of care. EMBED CODE I don't think I had a particularly good experience, some people have had a wonderful experience with OTs and social workers and they've helped the necessary people out enormously and I don't seem to have had that. so I wouldn't say it's just my experience has not been particularly great but yeah. I could do with light switches being altered in particular rooms, they've promised to do certain things that haven't got done, they've suggested things and they've never, they've said 'Oh we'll get back to you' and 'We're going to', they were going to put an intercom thing so that when I was bad and somebody came to the door I didn't have to come to answer the door I could have an intercom and that would be a suffice and that was going to be done and 'We'll get the information for you' and then nothing happens, and you don't want to badger people but you end up, when you've got the energy that's what you spending half your time is chasing up on things or, and that shouldn't have to be the case I think if, to me, I don't know an OT and social worker should be people who are your crutches that should be adding to your strength they shouldn't, I don't think should be leaving you on the wayside and you know to me that's their job to help you get back to some sort of normality and quite often, there's a few of us in this area who have actually gone, or informed social workers, or OTs about certain products or things that have come into place, or even care packages that have come in that they've been completely unaware of. Now we're finding it out, we've found out about it years later so surely they should have been finding out when it was implemented, and yeah you get fed up fighting for things and so I would say if you've got somebody who can fight for your corner then grab hold of them with both hands and let them do it for you because it's just wasted energy for yourself to be doing it and so that's another one, delegate that, yeah. OTs had supplied various gadgets and equipment (see 'Personal life and changes to the home'). Equipment for the kitchen included kettle tipppers, perching stools, bottle top removers, trolleys and non-slip mats (e.g. Dycem). Two people said these were very useful for different tasks such as stopping things slipping on a surface and removing jar tops. Several people had received aids for personal care and dressing, including bath boards and seats, bottom washers/wipers, raised toilet seats, long-handled hairbrushes, a sock aid and dressing stick. One woman had bought an electric toothbrush which helped; another still hoped to find something that would allow her to shampoo her own hair. People often found taps or showers difficult to turn on and had either been offered special tap turners, which fit over existing taps, or changed to lever taps which made it much easier. An OT visited one woman's home before she had surgery and helped with various aids. EMBED CODE Oh yes, of course, oh god yes, I've seen loads of OTs yeah. Certainly, especially in hospital, when you have joint replacement operation, that's one of the team who you will see. Obviously some people need adaptations to their home and things and they come and see you and make sure that you're all right, with aids and things. I've had many living aids over the years some of which have been of great use, others not so much [laughs]. Which ones would say have been of the most benefit? I'm a big fan of the, the picker upper as I call it, or the helping hand, or whatever you want to call it. Oh God I've got a Bath Master that sort of lowers you in and out of the bath, which has been, obviously I can't stand in the shower. Oh and then any number of things, things to brush your hair, things to wash your hair, raised toilet seats I mean invaluable really. Obviously I don't, my mother cooks for me, so I don't obviously, don't anything with the cooking and never did really in the kitchen. And a lot of the aids they gave us were for the kitchen, kettle tipppers and things like that and my mother doesn't really want the kitchen cluttered up with all kinds of gadgets for me to just to make a piece a toast once in a blue moon, you know. So they kind of ended up piled up in the attic [laughs]. But no, I mean a lot of them have been very, very useful. EMBED CODE I had some yeah, but the occupational therapist was, came to my house when I had my wrists replaced or before I had them done and a brilliant service I had from her 'cos things like, well even before I had the surgery, yeah before, because my hands were so sore I couldn't turn on the taps and oh phwao it was hopeless and so she brought all sorts of weird and wonderful things. I think probably all of which without exception I used after my hand surgery and found it very useful. I don't think I did very much when I was in hospital. It was, it was a home, a domestic service, support service that they offered which was very helpful, very helpful. What sort of things, what gadgets did you have? Well she first of all she left me a little trolley that I could, because I couldn't carry anything when I'd had my wrists done so I could bring something from the kitchen into here, just a little tiny, like a tea trolley, but it was higher than that. I had a gadget for sitting the kettle on which tipped the kettle, which was great. The taps, [pause] I don't know whether I should tell you the next one [laughter], she left me a washing-up sponge to wash my bottom with [laughter], sitting on the bidet, but better delete that one! I, yeah I think that was probably but they were and of course the taps were changed, oh that was marvellous, nothing you know, you can't turn on the tap in the morning, oh it's awful. But that was, those were the main things. Did you actually change the taps to...? They put new taps on so they had levers, so I didn't have to turn them. So you can still use them? Still got them. Yeah, marvellous, yeah. Other useful items included a 'Helping Hand' to pick up things from the floor, large key fobs to make them easier to turn and writing aids. One woman was worried that if she chose to have all the gadgets the OT suggested her home would look like an 'old person's home'. OTs also provided advice on how to protect joints and gave them splints for various joints. The most common were wrist splints to be worn for specific activities such as household chores, gardening, cycling, pushing pushchairs as well as at rest. People said they offered support when their wrists felt weak, stopped them twisting them and helped when their wrists were painful. However it was difficult to wear them for some tasks. Wrist splints worn at night supported their wrists in a good position and stopped them aching in the morning. One woman was unsure whether wearing them was a good idea as she said it made her wrists very stiff and it took a long time to get them moving. Wrist splints are usually made of strong elasticated material with a metal bar to keep the correct wrist angle and Velcro straps for fitting. One woman describes how she didn't like the look of those provided by the hospital and had found a company that made more attractive looking ones. EMBED CODE Well, the splint helps, it, it supports the wrist really, and it keeps the wrists still. I mean it's not a good idea to wear them all the time but it's a good idea to put them on when you're doing things like ironing or writing or like holding a book 'cos I find the telephone, if I have, if someone rings up and they're talking for a long time my joints kind of like seize up and they, they lock. And you'd said you'd managed to find some modern ones? Yes, yes. A couple of years ago I read a, I read an article in the Telegraph - I don't remember the lady's name off hand - but as a child she'd had problems and then as she got older she'd been diagnosed with RA and just couldn't bear the clumsy, dare I say it, National Health ones, which are fine, do the job but very soon look dirty and, you know, the, the velcro goes and everything. And I read the article and of course she had said that she was so fed up with this that she got a designer to design something that would do the job but, but would be sort of like, almost like a fashion item that you could wear. And they do them in different colours, black, cream, blue - I forget what else - and I sort of put the article, I shall follow that up, and I put it down and forgot all about it and then about 8 or 9 months later I thought 'Oh I'm going to get in touch with these people'. So I got on the Internet and ordered a pair and it, it was only when they came that I realised if I'd actually said that I had been diagnosed with the rheumatoid I wouldn't have had to pay the VAT on them, because that's an allowance they make. And these are wonderful, they're black lycra, mine and the, the actually splint is plastic. So you have to measure yourself, your wrist and I think the hand, take the wrist measurement and then they decide what size you need, whether it's small, medium or large and then when they come you actually put the plastic splint into hot water and then you put it back into the splint, the actual wrist material and mould it to fit your wrist. So it, it's, it's to fit you perfectly and I mean at the moment it's not a problem for me but the zip has a big ring at the bottom so you're not, for someone who's not very good with their fingers, you don't have the little zip, you have a ring pull on the bottom so you can just pull them on and off easily. And I would say the only down side is that, you know, you wouldn't keep a watch on of course because it's uncomfortable, so you would have to put that on the top. But the, the ring pull does tend to ride up a little bit so if you haven't got a sweater, a long sleeved sweater on, it would be a nuisance. But I mean like this time of the year when you would probably wear them more, they are a whole lot better because you can wear a jumper over the top and then it just looks like you've got a, a sort of half glove on. You know, so they are very comfortable. And of course they're completely washable so you just take out the plastic splint and throw them in the washing machine. You know, so you can use them for everything. So I am very impressed with those. Other splints were often specially made by the OTs to fit the individual and included thumb, finger, ankle, knee and leg splints. People said that some of these were good but others found them 'horrible' and chose not to wear them. The leg splints were worn at night to keep knees straight. One woman also had a neck collar, which she wore on car journeys, to stop unexpected jolts. One young woman had been given special gloves to wear at night to reduce the inflammation in her hands which she found helpful. Several more recently diagnosed respondents were not always willing to listen to the occupational therapist. They felt advice about protecting joints and damage that may restrict them did not apply to them because they felt they were not going to get that bad and they would not need gadgets. Similarly others felt that they had got over the worst part and their symptoms were improving with medication. However having met an OT they felt they could approach one in future for advice if they did have problems. Some people who had lived with RA for many years felt they had little left to learn from further visits to an OT. EMBED CODE I went to see the occ, the occupational therapist who was brilliant but by the, by the time I got to see her, you see the, I'd already done the hard bit without any help and I'd gone and she, she explained to me that I could wear splints, that I might, you know, if I wanted to I could have splints. She gave me some gloves which at that time it just, they're just, because all the swelling, 'cos I was, I'd swollen up you put these gloves on inside out 'cos of the, the, the, the seams, 'cos otherwise you get them, it sounds really stupid, you get up in the morning and you'd have lines on your hands where you've worn these gloves. And it helps to keep the swelling down. I don't use them now, I don't. I don't need them now. But they're things to help you write with 'cos I did need to, you know, I, at that time I, I, I didn't, I'd sign a cheque, you know, and it'd just be a scribble 'cos I couldn't shut my fingers properly. So yeah, the leaflets for me didn't help. I don't. I don't, I don't want to know about the long term, I wanted now. What's going to happen to me now? What's going to happen to me in a couple of weeks' time, you know. So that, it didn't, they didn't particularly help me 'cos I just didn't want to think 'I'm going to have to have splints. I'm going to have to have, you know, I'm going to have to have help with everything.' 'Cos you get things to help you with your zips, and oh no, no, no, it didn't. No, in fact, if anything it made me feel worse because I, I just remember thinking, 'I'm going to have to have all this. I'm going to, I'm going to have to need things to help me with my zip. I'm going to need things that you, you can, a gripper that you can help take the tops off, and so no. Just can't see it, oh no. Didn't help me at all. So when you saw the occupational therapist, I mean, you said they gave you a gripper for your pens. So there was something that oh were helpful? Yeah but, you see why I'd gone to see the occ, by the time I'd gone to see the occupational therapist I was starting to feel a lot better and I'd, but I still had the, you know, I, I still couldn't quite close my hands properly and, you know, I'd have a, so obviously my hands were the worst affected 'cos I couldn't grip anything properly. So by the time I'd gone to see her it, it started to get a lot better and by, by that stage as well I, I just adapted to everything. So, she, she didn't really help me. She gave me some good advice but she, quite scary as well, you know, you shouldn't put too much pressure on your hand, obviously where the, where they're all swollen up and things it's, there, you're going to do damage then. So she's, yeah she was quite frightening, you know. 'If you don't do this and you don't do that you're going to, you know, you have to find ways of adapt.' But you, you do that anyway. You do find that, you do, it's, it's, the same with everything, you, do find ways to adapt. So she, you know, that, she didn't really help me. Gave me some, you know, good advice but, she didn't really help me as it were. To see a hospital-based OT you will need a referral from your GP or rheumatologist, but you can also refer yourself to a community OT through social services. If you are having problems getting a referral, contact your local social services and ask for a needs assessment. You are entitled to this under the NHS and Community Care Act 1990. Last reviewed August 2016. Last updated September 2010. web design by



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